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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,246	08/08/2005	Eric Hollander	007166 01 US	2870

36234 7590 05/25/2010

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EXAMINER	
CLARK, SARA E	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
05/25/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,246	HOLLANDER, ERIC	
	Examiner	Art Unit	
	SARA E. CLARK	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,6-9,11-18,21,23-28 and 30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 4, 6-9, 11-18, 21, 23-28, and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL REJECTION

Receipt is acknowledged of Applicants' Amendments and Remarks, filed 7/27/2009.

Claims 3, 5, 10, 19, 20, 22, 29, and 31 are cancelled.

Claims 18 and 27 have been amended. The amendments are supported by Example 1 (table, spec. p. 28); thus, amended claims 18 and 27 contain no new matter.

No new claims have been added.

Thus, claims 1, 2, 4, 6-9, 11-18, 21, 23-28, and 30 now represent all claims currently pending and under consideration.

INFORMATION DISCLOSURE STATEMENT

No new Information Disclosure Statements (IDS) have been submitted.

WITHDRAWN OBJECTIONS/REJECTIONS

Objections

Due to the cancellation of claims 5 and 19, the objection to claims 5 and 19 is withdrawn.

Rejections under 35 USC §112

Due to the amendments to the claims, the rejection of claims 18 and 27 under 35 USC 112, first paragraph, for indefiniteness, has been withdrawn.

MAINTAINED REJECTIONS

The following rejection is maintained from the previous Office Action dated 4/2/2009, on the ground that the references cited therein continue to read on the limitations of the amended claims.

Rejections under 35 USC §112

Claims 1, 2, 4, 6-9, 11-18, 21, 23-28, and 30 stand rejected under 35 USC 112, first paragraph, for lack of written description with respect to the term "oxytocin analog." See below.

Rejections under 35 USC §102

Claims 1, 6, 12, 15, 23, and 28 stand rejected under 35 USC 102(b) as anticipated by Knauf. See below.

Claims 1, 2, 4, 6-9, 11, 12, 15-18, and 23-28 stand rejected under 35 USC 102(e) as anticipated by Quay. See below.

Rejections under 35 USC §103

Claims 13 and 14 stand rejected under 35 USC 103(a) as obvious over Knauf in view of Quay. See below.

Claims 21 and 30 stand rejected under 35 USC 103(a) as obvious over Knauf in view of Begley. See below.

RESPONSE TO ARGUMENTS

Applicant's arguments filed 7/27/2009 have been fully considered but they are not persuasive.

1. With respect to the rejection of claims 1, 2, 4, 6-9, 11-18, 21, 23-28, and 30 under 35 USC 112, first paragraph, for lack of written description, Applicant contends that (a) the term "analog" is commonly understood by those skilled in the art and thus has a definite meaning; and (b) in relation to the *Wands* factors, undue experimentation would not be required to practice the claimed invention (Remarks, pp. 8-9).

While the term "analog" is commonly understood in the art to refer generally to a class of closely related compounds, the term can refer to structural analogs (chemical compounds with a slightly altered chemical structure) as well as functional analogs (chemical compounds with similar properties). However, structural analogs may have a high chemical similarity, but they are not necessarily functional analogs; and they may have very different physical, chemical, biochemical, or pharmacological properties. Likewise, functional analogs have similar properties or effects *in vivo*, but they are not necessarily also structural analogs with a similar chemical structure (see Wikipedia entries, attached).

Thus, the boundaries of the term "analog" are indistinct, such that the compound species which are included and the compound species which are excluded by the term, with respect to a particular reference compound (here, "oxytocin analog"), have no natural boundary or commonly understood limit. The term "oxytocin analog"

encompasses, for example, any and all compounds having structural similarity to oxytocin, whether or not their functional properties *in vivo* resemble oxytocin; as well as any and all compounds having functional similarity to oxytocin (to include compounds not yet discovered), whether or not their chemical structure is similar. Thus, the basis of the written description rejection is that the disclosure does not apprise those skilled in the art which compound species the Applicant regards as "similar," structurally or functionally, and it is in this sense that the term "analog" has no commonly understood, defined limit.

The written description requirement of 35 USC 112, first paragraph, is distinct from the enablement requirement. Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was *in possession of the invention*, and that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon *"reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter*." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)). See MPEP §2163 *et seq*.

This rejection can be overcome by amending the claims to omit the term "analog" and/or to recite specific, defined compound species.

2. With respect to the rejection of claims 1, 6, 12, 15, 23, and 28 under 35 USC 102(b) as anticipated by **Knauf**, Applicant contends that the reference is merely a brief description of the personal beliefs of the inventor, containing false statements that render the reference suspect in its entirety, and thereby fails to provide an enabling disclosure (Remarks, pp. 10-12).

However, Knauf identifies children and adults with autism as a patient population which can be treated by the administration of the missing neurohormones oxytocin, vasopressin, and/or endorphins (p. 3, lines 26-36); and the claim recites a medicament comprising oxytocin, which implicitly discloses a method of exogenous administration of oxytocin to the claimed patient populations. The inventor's assertions may be oddly phrased, translated poorly into English, unsupported by experimental data, or perceived as politically incorrect; however, the reference nonetheless provides an enabling disclosure of the subject matter of claims 1, 6, 12, 15, 23, and 28.

Specifically, claims 1, 6, and 12 are drawn to methods of treating "an individual demonstrating behavioral characteristics associated with autism comprising the steps of: administering to said individual a composition comprising a therapeutically effective amount of oxytocin." Knauf explicitly discloses treatment of the distinct patient population "children and adults with autism" (p. 2, lines 55-59), treatment of which inherently results in the treatment of *behavioral characteristics associated with* autism, as recited by claims 1, 6, and 12.

Claims 15, 23, and 28 are drawn to methods of treating "an individual with a disorder including repetitive behaviors, social deficits, and cognitive deficits comprising

the steps of: administering to said individual a composition comprising a therapeutically effective amount of oxytocin." Knauf also discloses treatment of this patient population; for example, individuals with bulimia (p. 3, lines 9-12), a condition which is identified in the specification as a disorder including repetitive behavior (p. 6, lines 22-24), as recited by claims 15, 23, and 28.

Because the reference discloses a medicament comprising oxytocin, and a method of supplying it to children or adults with autism or to individuals with bulimia, until they develop a normal emotional life ("ein normales Gefühlsleben entwickeln," (p. 3, line 32), Knauf implicitly discloses administration of oxytocin in an amount that is therapeutically effective, as recited by claims 1, 6, 12, 15, 23, and 28.

3. With respect to the rejection of claims 1, 2, 4, 6-9, 11, 12, 15-18, and 23-28 under 35 USC 102(e) as anticipated by **Quay**, Applicant contends that the reference discloses treatment only of psychiatric disorders, not autism, which is a non-psychiatric, neurodevelopmental disorder (Remarks, pp. 12-13). However, the reference explicitly discloses treatment of autism. Although it may be mischaracterized as a psychiatric disorder, the patient population of individuals with autism is distinctly identified as amenable to treatment by the disclosed methods. Quay discloses at col. 6, lines 24-34:

> In other aspects of the invention, carbetocin and/or another long-acting oxytocin analogue is administered according to the foregoing methods in a coordinate treatment or prophylaxis protocol with an antidepressant, such as a selective serotonin reuptake inhibitor (SSRI) or serotonin reuptake inhibitor (SRI). In one embodiment, carbetocin is administered coordinately with an SSRI (e.g., fluvoxamine, paroxetine, sertraline or fluoxetine), or an SRI (e.g., clomipramine) to prevent, treat or alleviate the symptoms of a psychiatric disorder, such as obsessive compulsive disorder, **autism** or Prader-Willi syndrome.

See also Quay, col. 11, lines 40 and 46 (identifying autism). Further, the patient population recited by the claims is broader than individuals with autism *per se*; specifically, the claims are drawn to methods of treating individuals

- "demonstrating behavioral characteristics associated with autism" (claims 1, 2, 4, 6-9, and 11-13); and
- "with a disorder including repetitive behaviors, social deficits, and/or cognitive deficits" (claims 14-18 and 23-28).

Because the treatment of patients with autism inherently results in the treatment of behavioral characteristics associated with autism, the disclosure of Quay anticipates claims 1, 2, 4, 6-9, 11, and 12. Quay also discloses the treatment of, for example, obsessive-compulsive disorder (see above), which is identified in the specification as a disorder including repetitive behaviors (p. 6, lines 22-24). Therefore, the disclosure of Quay also anticipates claims 15-18 and 23-28.

4. With respect to the rejection of claims 13 and 14 as obvious over Knauf in view of Quay, Applicant contends that because (1) Knauf does not address the behavioral characteristics associated with autism, and (2) Quay does not disclose a method of treating autism, the references do not teach or suggest each and every claim limitation (Remarks, pp. 13-14). In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., specific behavioral characteristics associated autism) are not recited in the rejected claims. Although the claims are interpreted in light of the

specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). As discussed above, each and every claim limitation is explicitly, implicitly, or inherently disclosed by the cited references; therefore, the rejection of claims 13 and 14 is maintained.

5. With respect to the rejection of claims 21 and 30 as obvious over Knauf in view of Begley, Applicant contends that (1) Knauf does not address the behavioral characteristics associated with autism; (2) a skilled artisan would in no way take the Knauf reference seriously; and (3) a skilled artisan would not have been motivated to combine the references, because earlier work apparently indicated that autistic children with higher levels of oxytocin were correlated with lower interaction, daily living skills, and social awareness (Remarks, pp. 14-15, citing para. 0011 of the specification, US Pub. 2006/0105939).

Applicant's arguments with respect to the Knauf reference are addressed above.

Claims 21 and 30 are drawn to methods of treating a narrowly defined patient population by administering a composition comprising oxytocin. Specifically, claim 21 is drawn to "a method for treatment of an individual with a disorder including repetitive behaviors, social deficits, and cognitive deficits . . . wherein said disorder including social deficits is social anxiety disorder;" and claim 30 is drawn to an improvement in a method for treatment of an individual with a disorder including repetitive behaviors, social deficits, and cognitive deficits . . . wherein said disorder including social deficits is social anxiety disorder." Thus, the patient population encompassed by claims 21 and 30

does not require the presence of an autism spectrum disorder. While autistic individuals may be prone to social anxiety disorder, there is no evidence of record to suggest that this condition cannot exist independently of autism. This is evidenced by, for example, The Merck Manual (see attached), which describes social anxiety disorder as follows:

> ***Social phobia (social anxiety disorder):*** Social phobia is fear of and anxiety about being exposed to certain social or performance situations. These situations are avoided or endured with substantial anxiety. People with social phobia recognize that their fear is unreasonable and excessive.
>
> Fear and anxiety in people with social phobia often centers on being embarrassed or humiliated if they fail to meet expectations. Often the concern is that their anxiety will be apparent through sweating, blushing, vomiting, or trembling (sometimes as a quavering voice) or that the ability to keep a train of thought or find words to express themselves will be lost. Usually, the same activity performed alone produces no anxiety. Situations in which social phobia is common include public speaking, acting in a theatrical performance, and playing a musical instrument. Other potential situations include eating with others, signing their name before witnesses, or using public bathrooms.

Thus, in response to Applicant's argument that a skilled artisan would not have been motivated to arrive at the claimed invention, it is noted that the features upon which applicant relies (i.e., treatment of autism *per se*) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In addition, the patient population disclosed by Begley is autistic individuals who were observed to become more talkative following administration of oxytocin. As noted in the previous Office Action (4/2/2009, pp. 11-12),

> Begley et al. report that "[t]he social phobia of autism may be linked to the brain chemical oxytocin. This molecule, best known for inducing labor and lactation, also promotes maternal and other bonds and so has come to be known as the sociability molecule. When Hollander, this is in a quote from the Begley reference, administered oxytocin to five autistic patients, it made them four times more talkative and, according to

> the patients, twice as 'happy.'" The symptoms and boundaries of Social Anxiety Disorder are blurry, and not elaborated upon in the specification, but results such as these would reasonably be expected to be a desired outcome for individuals having social deficits or phobias.
>
> Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to be motivated to use oxytocin to treat symptoms of autism, as taught by Knauf and Begley et al., more specifically to alleviate the symptoms of Social Anxiety Disorder, with a reasonable expectation of success, since the clear-cut, positive results reported by Begley et al. in the treatment of autistic individuals would have suggested the use of oxytocin for such conditions.

Both Knauf and Begley disclose the treatment of autism by the administration of oxytocin, and Begley further teaches that administration of oxytocin promotes talkativeness and subjective feelings of happiness in autistic individuals, implicitly disclosing the efficacy of oxytocin in the treatment of disorders including social deficits, in particular social anxiety disorder.

CONCLUSION

Claims 1, 2, 4, 6-9, 11-18, 21, 23-28, and 30 are rejected.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARA E. CLARK whose telephone number is (571) 270-7672. The examiner can normally be reached on Mon - Thu, 7:30 am - 5:00 pm (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass, can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SARA E. CLARK/
Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612